

**REMARKS:**

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

**Claim Rejections – 35 U.S.C. § 101**

Applicant acknowledges the quotation of 35 U.S.C § 101:

Claims 1-6 and 11-23 stand rejected under 35 U.S.C § 101 as being directed to non-statutory subject matter. More specifically, claims 1-6 and claims 11-23 stand rejected as being directed to non-statutory subject without requiring performance of a result outside of a computer or data manipulation method with reference to MPEP 2106, Part IV, subpart B.

In consideration of the amendment to independent claim 1 presented, applicant believes that the 35 U.S.C § 101 rejection of claim 1 has been overcome and that the claim and dependent claims are now in condition for allowance.

Applicant respectfully traverses the finding of the Office that independent claims 4, 11, 13, 14, 16, 17 and 19-23 are directed to non-statutory subject matter. Applicant believes that these independent claims and the claims that depend from them are directed to statutory subject matter. As an example, claim 4 is directed to the identification of one or more genes linked to a cellular phenotype and claim 16 is directed to a method of screening for a drug that modulates an expression of a gene. For similar reasons, the remaining independent claims are believed to be directed to statutory subject matter outside of a computer or data manipulation method. Accordingly, Applicant believes that these claims are in condition for allowance.

**Claim Rejections – 35 U.S.C. § 112**

Applicant acknowledges the quotation of 35 U.S.C § 112, second paragraph.

Claims 1-6, 12, 15, 16, and 18 stand rejected under 35 U.S.C § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More specifically, independent claim 1 stands rejected for setting forth a formula with numerous undefined parameters therein. In view of the amendment to claim 1 presented, Applicant believes that the 35 U.S.C. § 112 rejection of claim 1 has been overcome and that claim 1 is in condition for allowance.

Claims 2 and 5 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office contends that the formulas are presented with numerous undefined parameters and that it is unclear whether generic parameters are meant or for someone attempting to understand the claim to search through the specification to reveal what values are meant thereby. The Applicant respectfully traverses the finding of the Office. Applicant believes that the Office has not established a prima facie case of indefiniteness. The Office has stated that it is unclear whether generic parameters are meant or for someone attempting to understand the claim to search through the specification to reveal what values are meant thereby. However, for a prima facie case of indefiniteness to be established, the Office must interpret the claims in light of the specification and interpret the claims as one of ordinary skill in the art would interpret them. The Applicant believes that one of ordinary skill in the pertinent art, when reading the claim in light of the supporting specification, would be able to ascertain with a reasonable degree of precision and particularity the specific area set off and circumscribed by the claim. As such, Applicant believes that the claims presented are definite as viewed from the vantage point of a person of ordinary skill in the art and that the prima facie case of indefiniteness has not been established.

Claim 15 has been amended to correct the dependency and overcome the U.S.C. § 112 rejection cited and is now believed to be in condition for allowance.

In view of the amendment to the claims, Applicant believes that the 35 U.S.C § 112 rejection has been overcome and that the claims are in condition for allowance.

#### **Claim Rejections – 35 U.S.C. § 102**

Applicant acknowledges the quotation of 35 U.S.C § 102(a) and (e)(2).

Claims 13-15, 19 and 21-23 stand rejected under 35 U.S.C § 102(a) and (e)(2) as being anticipated by Cabib et al. (U.S. Patent No. 5,784,162).

The Office states that Cabib et al. discloses the practice of imaging for biological research and medical diagnostics in the abstract wherein the last line therein indicates the interpretation of data using a mathematical algorithm. With specific reference to Claim 13, the Office cites column 5, line 61 through column 6, line 63 of Cabib as describing the imaging as being performed as directed to nucleic acids, via hybridization, and to distinguish cancer from healthy cells.

Applicant respectfully traverses the finding of the Office. Claim 13 of the present invention provides a method for identifying in a library a gene or set of genes linked to metastatic properties of a cancer. The steps include, providing a nucleic acid material from a suspected cancerous sample, hybridizing the sample-derived probes, to the library, detecting the differences between hybridization results of the sample and a reference standard, recording the differences to form a first set of data, analyzing protein expression data to form a second set of data, and combining said first set of data and said second set of data to identify the gene or set of genes which govern metastatic properties of the cancer. Cabib does not describe such a method. More specifically, Cabib does not describe analyzing protein expression data to form a second set of data, and combining the first set of data with the second set of data. Protein expression is defined by the present invention beginning in the last paragraph of pg. 30 as a means of quantitatively measuring protein levels of gene expression to characterize biological processes and decipher the mechanism of gene expression control. The specification states that while gene expression may be directly linked to mRNA levels within the cell, it is not always the case that mRNA levels predict protein levels and that it is determined that the comprehensive evaluation of protein expression may be equally as important as the evaluation of mRNA expressions. As such, the step of analyzing protein expression data is not equivalent to imaging directed to nucleic acids as described by Cabib. Therefore, Cabib does not describe the step of analyzing protein expression data to form a second set of data as disclosed and claimed by the present invention. For these reasons, Applicant does not believe that Cabib et al. anticipates Claim 13 of the present invention.

Claims 14 and 15 has been amended to be dependent upon claim 13, which has been shown to be allowable for the reasons described above.

The Office has not identified the reasons for the rejection of claims 19 and 21-23 in view of Cabib. Applicant has addressed the rejections cited by the Office in the Action and requests that specific rejections of claims 19 and 21-23 be presented or that the claims be allowed.

For the reasons cited above, Applicant believes that the claims presented in this amendment are not anticipated by Cabib et al. and are therefore believed to be in condition for allowance.

The remaining claims are dependent upon the independent claims that have been shown to be allowable, and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

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Dated: May 24, 2004

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CERTIFICATE OF FACSIMILE TRANSMISSION

(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 1631, Attn.: Ardin H. Marschel, (703) 872-9306 on May 24, 2004.

Dated: May 24, 2004

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